

Application No. 10/805,816  
Amendment dated August 7, 2006  
Reply to Office Action dated April 5, 2006

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### REMARKS/ARGUMENTS

The Office Action dated April 5, 2006, has been reviewed in detail and Claims 1 and 3-7 have been amended herein, and Claim 2 has been cancelled, in the sincere effort to place the claims in condition for allowance.

Support for the amendment to independent Claim 1 and 7 can be found in paragraphs 17-19 of the specification. Claims 3, 6 and 7 have been amended to make them better conform with the changes made to their base claim, Claim 1. Also, independent Claims 13 and 24 have been amended herein solely for the purpose of correcting an antecedent and grammatical error.

Applicant retains the right to pursue broader claims via a continuing application under 35 U.S.C. § 120.

#### Double Patenting:

*The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignee. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g. In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1929).*

*A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.*

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*Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).*

*Claims 1-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 10/911,755 in view of Michaeli (US Patent No. 6,328,694 B1). The claims of the '755 application teaches all the limitations of the claimed subject matter except for mentioning specifically the step or structure for using the pulsatile technique for pressure measurement. Michaeli teaches in col. 13, line 4, the step or structure for measuring pressure using pulsatile technique for diagnosing compartment syndrome (col. 13, line 3). Therefore, it would have been obvious to an ordinary skill in the art, at the time the invention was made to modify the invention of the '755 application such that it includes a step or structure for using pulsatile technique in order to diagnose compartment syndrome more accurately.*

*This is a provisional obviousness-type double patenting rejection.*

In response to this provisional rejection it is respectfully pointed out that the instant case was filed earlier than the reference case. The instant case was filed March 22, 2004, and the reference case (co-pending Application No. 10/911,755) was filed August 2, 2004. Additionally, it should be noted that because the reference case apparently has not yet been examined, no potential patent term extension given to the instant case should extend beyond the expected patent term of the reference case should it eventually issue. Additionally, MPEP Section 804 (B), entitled "Between Copending Applications-Provisional Rejections" states, inter alia, that:

*The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in >at least< one of the applications.\*\**

Because this double patenting rejection is the only current rejection against Claims 13-24, and because Claims 1-12 have been amended herein in a manner that is believed to make them fully distinguish from the applied art (please see remarks immediately below), therefore, it is respectfully submitted that it would be proper for the withdrawal of this provisional rejection at this time.

Based on the above, reconsideration and withdrawal of the instant rejection are respectfully requested.

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**Claim Rejection Under 35 U.S.C. §102:**

The Examiner rejected Claims 1-12 under 35 U.S.C. §1-2. Specifically, the Examiner stated:

*Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Michaeli (US 6,328,694 B1). Michaeli teaches in col. 12, line 42 – col. 13, line 4, a process for diagnosing compartment syndrome using ultrasonic pulsatile tomography which inherently includes the steps of assessing a body compartment configuration and identifying the effect of pulsatile components on at least one dimension of the body compartment.*

The Michaeli reference, as understood, discloses a method for tissue resonance analysis. Michaeli teaches the use of an ultrasound probe to propagate ultrasonic pulses through the head of a patient, to measure intracranial pressure. Reflected signals are received and processed to generate an echo encephalogram (Echo EG) signal, which is plotted as a function of amplitude vs. distance. A desired portion of this signal, corresponding to a selected distance from the ultrasound probe, is integrated to generate an echo pulsograph (EPG) signal. Using an electrocardiograph (ECG) signal for the same patient as a reference, the EPG signal is used to provide information regarding the physiological state of the tissue at the chosen depth (see, Michaeli, col. 7, lines 4-32). Specifically, Michaeli teaches the EPG signal can be used to calculate a quantitative measure of intra cranial pressure at a desired location in the brain.

Michaeli's Fig. 4 is a plot of an EPG waveform "which is derived from a corresponding Echo EG signal (not shown) and an ECG waveform generated from the ECG electrodes." The ECG waveform is used to identify the cardiac systole and provide a reference point for interpreting the EPG waveform. The EPG is defined as the integral of the Echo EG waveform across the gated portion of the Echo EG waveform. In Fig. 4, a corresponding peak in an EPG waveform following a cardiac systole is divided into portions of interest 403, 404 and 405, which portions identify the pulsatility characteristics of the brain. Michaeli teaches that these characteristics can be used to mathematically determine a quantitative indication of ICP, for example, one formula disclosed is:  $ICP_{\text{maximum}} = \rho(t_1/T) * [t_1/T] - \beta$  (please see specification for

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identification of symbols). Michaeli's Fig. 5, "is a graph of the variable  $p$  as a function of  $t/T$ , and also as a function of the second resonant frequency of the EPG waveform (see, Michaeli, column 17 line 3 to column 18 line 36).

Claim 1 of the instant invention, as amended herein, recites:

A process for measuring pressure buildup in one or more body compartments that encases muscular tissue, comprising the steps of:  
transmitting ultrasonic waves into a body compartment;  
capturing a sequence of reflections of the transmitted ultrasonic;  
converting the ultrasonic sequence into an electrical sequence;  
mathematically manipulating the electrical sequence such that amplitude changes of the manipulated sequence, at a substantially constant frequency, correspond to phase changes of the ultrasonic sequence;  
analyzing amplitude changes of the manipulated sequence to identify the effect of pulsatile components on at least one surface layer of the body compartment; and  
categorizing pressure build up in the body compartment based on the identified effect.

It is respectfully submitted that the instant invention, as now recited in independent Claim 1, is not anticipated by the Michaeli reference. It is submitted that the Michaeli reference does not disclose the steps of: "mathematically manipulating the electrical sequence such that amplitude changes of the manipulated sequence, at a substantially constant frequency, correspond to phase changes of the ultrasonic sequence" and "analyzing amplitude changes of the manipulated sequence to identify the effect of pulsatile components on at least one surface layer of the body compartment." Rather, the Michaeli reference, as explained above, analyzes an echo pulsograph (EPG) signal, derived from a desired portion of a echo encephalogram (Echo EG) signal, to identify pulsatility components of the brain. This EPG waveform is then used to provide a quantitative indication of ICP.

Additionally, dependent Claim 7 is believed to even further distinguish from the Michaeli reference as it has been amended herein to recite:

The process of claim 6, wherein the step of mathematically manipulating the electrical sequence such that amplitude changes of the manipulated sequence, at a

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substantially constant frequency, correspond to phase changes of the ultrasonic sequence  
comprises utilizing the Fourier Transform method.

Based on the above, independent Claim 1 and dependent Claim 7 are now believed to fully distinguish from the Michaeli reference, and to thus be in condition for allowance. Claim 2 has been cancelled herein rendering this rejection as to it moot. Because Claims 3-6 and 8-12 (as well as Claim 7) depend from Claim 1, they too are now believed to be in condition for allowance by virtue of this dependency.

Reconsideration and withdrawal of the present rejection is respectfully requested.

#### CONCLUSION

It is submitted that the Applicants have submitted new and unique Ultrasonic Apparatus And Method to Assess Compartment Syndrome. In view of the above, it is submitted that Claims 1-24 are in condition for allowance. Therefore, it is requested that a Notice of Allowance be issued at an early date.

Respectfully submitted,



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